2005 – 2006 LEGISLATURE

LRB-3021/P1
PJH:

PRELIMINARY DRAFT - NOT READY FOR INTRODUCTION

AN ACT ...; **relating to:** the wholesale distribution of prescription drugs, and granting rule-making authority.

Analysis by the Legislative Reference Bureau

This is a preliminary draft. An analysis will be provided in a later version.

The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:

SECTION 1. 450.01 (1m) of the statutes is created to read:

450.01 **(1m)** "Authentication" means verification, before distributing a prescription drug, that each transaction listed on a pedigree has occurred.

SECTION 2. 450.01 (2m) of the statutes is created to read:

450.01 **(2m)** "Chain pharmacy warehouse" means a physical location for drugs or devices that acts as a central warehouse and performs intracompany sales or transfers of the drugs or devices to a group of chain pharmacies that have the same common ownership and control.

SECTION 3. 450.01 (9) of the statutes is amended to read:

450.01 **(9)** "Distributor" means a person licensed by the board under s. ~~450.07 (2).~~ 450.071

History: 1985 a. 146; 1987 a. 65; 1991 a. 114; 1995 a. 448; 1997 a. 27, 68; 1997 a. 237 s. 727m.

SECTION 4. 450.01 (11m) of the statutes is created to read:

450.01 **(11m)** "Facility" means a facility of a wholesale distributor where prescription drugs are stored, handled, repackaged, or offered for sale.

SECTION 5. 450.01 (11r) of the statutes is created to read:

450.01 **(11r)** "Intracompany sales" means any transaction or transfer between any division, subsidiary, parent, or affiliated or related company under common ownership and control of a corporate entity.

SECTION 6. 450.01 (13r) of the statutes is created to read:

450.01 **(13r)** "Normal distribution channel" means a chain of custody for a medication that goes from a manufacturer to a wholesale distributor to a pharmacy or a chain pharmacy warehouse to a patient.

SECTION 7. 450.01 (14m) of the statutes is created to read:

450.01 **(14m)** "Pedigree" means a document or electronic file containing information that records each distribution of a prescription drug within the distribution channel.

SECTION 8. 450.01 (21m) of the statutes is created to read:

450.01 **(21m)** "Repackage" means to repack or otherwise change the container, wrapper, or label of a prescription drug. Repackaging does not include the administration, delivery, or distribution of a prescription drug by a pharmacist to a patient.

SECTION 9. 450.01 (23) of the statutes is created to read:

450.01 **(23)** "Wholesale distribution" does not include:

(a) Intracompany sales of prescription drugs.

(b) The administration, delivery, dispensing, sale, purchase, distribution, trade, or transfer of a prescription drug or offer to sell, purchase, distribute, trade, or transfer a prescription drug for emergency medical reasons.

(c) The distribution of prescription drug samples by a manufacturer's representative.

(d) Drug returns, when conducted by a hospital, health care facility, retail pharmacy, or charitable institution.

(e) The sale of minimal quantities of prescription drugs by retail francais to licensed health care providers for office use.

(f) The practice of pharmacy.

(g) The sale, transfer, merger, or consolidation of all or part of the business of a pharmacy or pharmacies from or with another pharmacy or pharmacies, whether accomplished as a purchase and sale of stock or business assets.

SECTION 10. 450.01 (24) of the statutes is created to read:

450.01 **(24)** "Wholesale distributor" means a person engaged in the wholesale distribution of prescription drugs, including but not limited to repackagers, own–label distributors, private label distributors, jobbers, brokers, warehouses, including manufacturers' and distributors' warehouses, and drug wholesalers or distributors, independent wholesale drug traders, and retail pharmacies or chain pharmacy warehouses that conduct wholesale distribution.

SECTION 11. 450.07 (title) of the statutes is amended to read:

450.07 (title) **Manufacturers ~~and distributors~~; licensure.**

History: 1985 a. 146; 1991 a. 39.

SECTION 12. 450.07 (2) of the statutes is repealed.

SECTION 13. 450.07 (3) of the statutes is repealed.

SECTION 14. 450.07 (4) (b) (intro.) of the statutes, as affected by 2005 Wisconsin Act 14, is amended to read:

450.07 **(4)** (b) (intro.) The board shall adopt rules prescribing minimum standards for manufacturing ~~and distributing~~ drugs. insert attached

History: 1985 a. 146; 1991 a. 39.

SECTION 15. 450.071 of the statutes is created to read:

450.071 Wholesale distributors; licensure. (1) No person may engage in the wholesale distribution of a prescription drug in this state without obtaining a license, for each facility it operates, from the board.

(2) An applicant shall submit a form provided by the board showing all of the following, and swear or affirm the truthfulness of each item in the application:

(a) The name, business address, and telephone number of the applicant.

(b) All trade or business names used by the applicant.

(c) Names, addresses, and telephone numbers of contact persons for all facilities used by the applicant for the storage, handling, and distribution of prescription drugs.

(d) The type of ownership or operation for the applicant's business.

(e) If the applicant's wholesale distribution business is a partnership, the name, address, title, and telephone number of each partner, and the name of the partnership.

(f) If the applicant's wholesale distribution business is a corporation, the name, address, title, and telephone number of each corporate officer and director, the name of the corporation, and the state of incorporation.

Insert on p. 4

no # Rules adopted under this paragraph may not impose requirements regarding the storage of a controlled substance in a safe, a steel cabinet, a vault, or any other secure storage compartment, area, room, or building unless one of the following applies:

(g) If the applicant's wholesale distribution business is a sole proprietorship, the name of the sole proprietor and the name of the business entity.

(h) A list of all licenses and permits issued to the applicant by any other state that authorizes the applicant to purchase or possess prescription drugs.

(i) The name, address, and telephone number of a designated representative.

(j) For each person listed in par. (i), a personal information statement that contains all of the following:

1. The person's date and place of birth.

2. The person's places of residence for the past 7 years.

3. The person's occupations, positions of employment, and offices held during the past 7 years.

4. The name and addresses for each business, corporation, or other entity listed in subd. 3.

5. A statement regarding whether the person has been, during the past 7 years, the subject of any proceeding for the revocation of any license or been prosecuted for any criminal offense, and the disposition of the proceeding or prosecution.

6. A statement regarding whether the person has been, during the past 7 years, enjoined, either temporarily or permanently, from possessing, controlling, or distribution any prescription drug, and a description of the circumstances surrounding the injunction.

7. A description of any involvement by the person with any business, including investments, other than the ownership of stock in a publicly traded company or mutual fund, during the past 7 years, that manufactured, administered, prescribed, distributed, or stored pharmaceutical products or drugs, and a list of any lawsuits in which such business were named as a party.

8. A photograph of the person taken within the previous 30 days.

(3) Upon receipt of the application and information required in sub. (2), the board shall conduct a physical inspection of the facility from which the applicant intends to engage in the wholesale distribution of prescription drugs.

(4) The board shall grant a license to the applicant to engage in the wholesale distribution of prescription drugs if the inspection conducted pursuant to sub. (3) satisfies requirements adopted by the board for wholesale distribution facilities and if the designated representative listed by applicant:

(a) Is at least 21 years old.

(b) Has been employed full time for at least 3 years in a pharmacy or with a wholesale prescription drug distributor in a capacity related to the administration, dispensing, and distribution of, and recordkeeping related to, prescription drugs.

(c) Has received a score of 75 percent or more on an examination designed and administered by the board that tests the applicant's knowledge of state and federal laws regarding the wholesale distribution of prescription drugs.

(d) Is employed by the applicant full time in a managerial level position.

(e) Is physically present at the wholesale prescription drug distributor's facility during regular business hours and is involved in and aware of the daily operation of the wholesale prescription drug distributor. This paragraph does not preclude the designated representative from taking authorized sick leave and vacation time or from being absent from the facility for other authorized business or personal purposes.

(f) Is a designated representative for only one applicant at any given time.

(g) Has not been convicted of violating any federal, state, or local law relating to wholesale or retail prescription drug distribution or distribution of a controlled substance.

(h) Has not been convicted of a felony.

(i) Submits to the department 2 fingerprint cards, each bearing a complete set of the applicant's fingerprints. The department of justice may provide for the submission of the fingerprint cards to the federal bureau of investigation for the purposes of verifying the identification of the applicant and obtaining the applicant's criminal arrest and conviction record.

(5) The board may set, by rule, continuing education requirements for designated representatives under this section.

(6) The board may determine, by rule, requirements for surety bonding or other liability coverage that each wholesale distributor licensed under this section s. 450.071 shall carry in order to be licensed.

SECTION 16. 450.072 of the statutes is created to read:

450.072 Wholesale distributors; restrictions on transactions. (1) A wholesale distributor shall receive prescription drug returns or exchanges from a pharmacy or chain pharmacy warehouse pursuant to the terms and conditions of the agreement between the wholesale distributor and the pharmacy or chain pharmacy warehouse. Returns or exchanges made under this section shall not be subject to the requirements of s. 450.073, but no wholesale distributor shall permit the the entry of adulterated or counterfeit product during a return or exchange of product.

(2) (a) A manufacturer or wholesale distributor may distribute a prescription drug only to a person who is licensed or authorized by the state to receive a prescription drug. The manufacturer or wholesale distributor has an affirmative

duty to verify the person's license or state authorization before it distributes a prescription drug to the person.

(b) A manufacturer or wholesale distributor may distribute a prescription drug only to the premises listed on the person's license or authorization unless all of the following are true:

1. The manufacturer or wholesale distributor distributes the prescription drugs to an authorized agent of the person at the premises of the manufacturer or wholesale distributor.

2. The manufacturer or wholesale distributor documents the authorized agent's name and address.

3. This method of distribution is necessary to promote or protect the health or safety of the authorized agent's patient.

(d) A manufacturer or wholesale distributor may distribute a prescription drug to a hospital pharmacy receiving area if a licensed pharmacist or another authorized recipient signs, at the time of the distribution, a receipt that shows the type and quantity of prescription drugs distributed.

(e) No manufacturer or wholesale distributor may accept payment for, or allow the use of, a person's credit to establish an account for the purchase of a prescription drug from any person other than the owner of record, the chief executive officer, or the chief financial officer listed on the license or authorization of a person who may receive prescription drugs. Any account established for the purchase of prescription drugs shall bear the name of the licensed or authorized Persian.

SECTION 17. 450.073 of the statutes is created to read:

450.073 Wholesale distributors; pedigree. (1) Each wholesale distributor shall establish and maintain an inventory and record of all transactions regarding

the receipt and distribution or other disposition of a prescription drug. The records shall include a pedigree for each prescription drug that leave the normal distribution channel. This section does not apply to a retail pharmacy or a chain pharmacy warehouse unless the pharmacy or chain pharmacy warehouse engages in the wholesale distribution of prescription drugs.

(2) A pedigree shall contain all necessary identifying information concerning each sale or point of distribution in the chain of the distribution of the prescription drug from the manufacturer until final sale or distribution to a pharmacy or a person dispensing or distributing the prescription drug. At a minimum, the pedigree shall include:

(a) The name, address, telephone number, and, if available, electronic mail address of each recipient or distributor of the prescription drug in the chain of distribution, until the final sale or distribution described in sub. (2) (intro).

(b) The address of each location from which the prescription drug was distributed, if different from the address provided in par. (a).

(c) The date of each distribution.

(d) Certification that each recipient authenticated the pedigree before distribution the prescription drug to the next point in the chain of distribution.

(e) The name, dosage strength, size and number of containers, lot number, and name of the manufacturer for each prescription drug.

(3) The board may require, after December 31, 2007, wholesale distributors to maintain an electronic pedigree. The board may determine, after consultation with prescription drugs manufacturers, wholesale distributors, and pharmacies, when to require all wholesale distributors to maintain an electronic pedigree.

(4) Each person who is engaged in the wholesale distribution of a prescription drug, including a repackager but not including the original manufacturer of the prescription drug, and who possesses a pedigree for the prescription drug shall verify that each transaction recorded on the pedigree has occurred before the person may distribute the prescription drug.

(5) Each pedigree shall be maintained by the final recipient in the chain of distribution and by the wholesale distributor for 3 years from the date of sale or distribution.

SECTION 18. 450.074 of the statutes is created to read:

450.074 Wholesale distributors; penalties. (1) A person who violates a provision of ss. 450.071 to 450.073 is guilty of a Class E felony.

(2) Any person who engages in misrepresentation or fraud in order to distribute a prescription drug under ss. 450.071 to 450.073 is guilty of a Class E felony.

(3) Any person who adulterates, misbrands, or counterfeits a prescription drug in order to distribute the adulterated, misbranded, or counterfeit prescription drug under ss. 450.071 to 450.073 is guilty of a Class E felony.

(END)

2005 – 2006 LEGISLATURE LRB-3021/P1
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PRELIMINARY DRAFT – NOT READY FOR INTRODUCTION

AN ACT ***to repeal*** 450.07 (2) and 450.07 (3); ***to amend*** 450.01 (9), 450.07 (title) and 450.07 (4) (b) (intro.); and ***to create*** 450.01 (1m), 450.01 (2m), 450.01 (11m), 450.01 (11r), 450.01 (13r), 450.01 (14m), 450.01 (21m), 450.01 (23), 450.01 (24), 450.071, 450.072, 450.073 and 450.074 of the statutes; **relating to:** the wholesale distribution of prescription drugs, granting rule-making authority, and providing a penalty.

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(c) The distribution of prescription drug samples by a manufacturer's representative.

(d) Drug returns, when conducted by a hospital, health care facility, ~~retail pharmacy,~~ or charitable institution.

(e) The sale of minimal quantities of prescription drugs by retail franchises to licensed health care providers for office use.

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~~450.07 **(4)** (b) (intro.) The board shall adopt rules prescribing minimum standards for manufacturing and distributing drugs. Rules adopted under this paragraph may not impose requirements regarding the storage of a controlled substance in a safe, a steel cabinet, a vault, or any other secure storage compartment, area, room, or building unless one of the following applies:~~

SECTION 15. 450.071 of the statutes is created to read:

450.071 Wholesale distributors; licensure. ~~**(1)** No person may engage in the wholesale distribution of a prescription drug in this state without obtaining a license, for each facility it operates, from the board.~~ (Insert A)

(2) An applicant shall submit a form provided by the board showing all of the following and swear or affirm the truthfulness of each item in the application:

(a) The name, business address, and telephone number of the applicant.

(b) All trade or business names used by the applicant.

(c) Names, addresses, and telephone numbers of contact persons for all facilities used by the applicant for the storage, handling, and distribution of prescription drugs.

(d) The type of ownership or operation for the applicant's business.

each wholesale needs a license, but not each facility.

manufacturers are exempt

for licenses

(e) If the applicant's wholesale distribution business is a partnership, the name, address, title, and telephone number of each partner, and the name of the partnership.

(f) If the applicant's wholesale distribution business is a corporation, the name, address, title, and telephone number of each corporate officer and director, the name of the corporation, and the state of incorporation.

(g) If the applicant's wholesale distribution business is a sole proprietorship, the name of the sole proprietor and the name of the business entity.

(h) A list of all licenses and permits issued to the applicant by any other state that authorizes the applicant to purchase or possess prescription drugs.

(i) The name, address, and telephone number of a designated representative.

(j) For the person listed in par. (i), a personal information statement that contains all of the following:

1. The person's date and place of birth.

2. The person's places of residence for the past 7 years.

3. The person's occupations, positions of employment, and offices held during the past 7 years.

4. The name and addresses for each business, corporation, or other entity listed in subd. 3.

5. A statement regarding whether the person has been, during the past 7 years, the subject of any proceeding for the revocation of any license or been prosecuted for any criminal offense, and the disposition of the proceeding or prosecution.

6. A statement regarding whether the person has been, during the past 7 years, enjoined, either temporarily or permanently, from possessing, controlling, or

distributing any prescription drug, and a description of the circumstances surrounding the injunction.

7. A description of any involvement by the person with any business, including investments, other than the ownership of stock in a publicly traded company or mutual fund, during the past 7 years, that manufactured, administered, prescribed, distributed, or stored pharmaceutical products or drugs, and a list of any lawsuits in which such a business was named as a party.

8. A photograph of the person taken within the previous 30 days.

(3) Upon receipt of the application and information required in sub. (2), the board shall conduct a physical inspection of the facility from which the applicant intends to engage in the wholesale distribution of prescription drugs.

(4) The board shall grant a license to the applicant to engage in the wholesale distribution of prescription drugs if the inspection conducted pursuant to sub. (3) satisfies requirements adopted by the board for wholesale distribution facilities and if the designated representative listed by applicant:

(a) Is at least 21 years old.

(b) Has been employed full time for at least 3 years in a pharmacy or with a wholesale prescription drug distributor in a capacity related to the administration, dispensing, and distribution of, and record keeping related to, prescription drugs.

(c) Has received a score of 75 percent or more on an examination designed and administered by the board that tests the applicant's knowledge of state and federal laws regarding the wholesale distribution of prescription drugs.

(d) Is employed by the applicant full time in a managerial level position.

(e) Is physically present at the wholesale prescription drug distributor's facility during regular business hours and is involved in and aware of the daily operation of

the wholesale prescription drug distributor. This paragraph does not preclude the designated representative from taking authorized sick leave and vacation time or from being absent from the facility for other authorized business or personal purposes.

(f) Is a designated representative for only one applicant at any given time.

(g) Has not been convicted of violating any federal, state, or local law relating to wholesale or retail prescription drug distribution or distribution of a controlled substance.

(h) Has not been convicted of a felony.

(i) Submits to the department 2 fingerprint cards, each bearing a complete set of the applicant's fingerprints. The department of justice may provide for the submission of the fingerprint cards to the federal bureau of investigation for the purposes of verifying the identification of the applicant and obtaining the applicant's criminal arrest and conviction record.

(5) The board may set, by rule, continuing education requirements for designated representatives under this section.

(6) ~~The board may determine, by rule, requirements for surety bonding or other liability coverage that each wholesale distributor licensed under this section shall carry in order to be licensed.~~ (Insert B)

SECTION 16. 450.072 of the statutes is created to read:

450.072 Wholesale distributors; restrictions on transactions. (1) A wholesale distributor shall receive prescription drug returns or exchanges from a pharmacy or chain pharmacy warehouse pursuant to the terms and conditions of the agreement between the wholesale distributor and the pharmacy or chain pharmacy warehouse. Returns or exchanges made under this section shall not be subject to the

requirements of s. 450.073, but no wholesale distributor shall permit the entry of adulterated or counterfeit product during a return or exchange of product.

~~(2) (a) A manufacturer or wholesale distributor may distribute a prescription drug only to a person who is licensed or authorized by the state to receive a prescription drug. The manufacturer or wholesale distributor has an affirmative duty to verify the person's license or state authorization before it distributes a prescription drug to the person.~~ (Insert C)

(b) A manufacturer or wholesale distributor may distribute a prescription drug only to the premises listed on the person's license or authorization unless all of the following are true:

1. The manufacturer or wholesale distributor distributes the prescription drugs to an authorized agent of the person at the premises of the manufacturer or wholesale distributor.

2. The manufacturer or wholesale distributor documents the authorized agent's name and address.

3. This method of distribution is necessary to promote or protect the health or safety of the authorized agent's patient.

(c) A manufacturer or wholesale distributor may distribute a prescription drug to a hospital pharmacy receiving area if a licensed pharmacist or another authorized recipient signs, at the time of the distribution, a receipt that shows the type and quantity of prescription drugs distributed.

(d) No manufacturer or wholesale distributor may accept payment for, or allow the use of, a person's credit to establish an account for the purchase of a prescription drug from any person other than the owner of record, the chief executive officer, or the chief financial officer listed on the license or authorization of a person who may

receive prescription drugs. Any account established for the purchase of prescription drugs shall bear the name of the licensed or authorized person.

SECTION 17. 450.073 of the statutes is created to read:

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(2) A pedigree shall contain all necessary identifying information concerning each sale or point of distribution in the chain of the distribution of the prescription drug from the manufacturer until final sale or distribution to a pharmacy or a person dispensing or distributing the prescription drug. At a minimum, the pedigree shall include:

(a) The name, address, telephone number, and, if available, electronic mail address of each recipient or distributor of the prescription drug in the chain of distribution, until the final sale or distribution that is described in sub. (2) (intro.).

(b) The address of each location from which the prescription drug was distributed, if different from the address provided in par. (a).

(c) The date of each distribution.

(d) Certification that each recipient authenticated the pedigree before distribution of the prescription drug to the next point in the chain of distribution.

(e) The name, dosage strength, size and number of containers, lot number, and name of the manufacturer for each prescription drug.

(3) The board may require, after December 31, 2007, wholesale distributors to maintain an electronic pedigree. The board may determine, after consultation with prescription drugs manufacturers, wholesale distributors, and pharmacies, when to require all wholesale distributors to maintain an electronic pedigree.

(4) Each person who is engaged in the wholesale distribution of a prescription drug, including a repackager but not including the original manufacturer of the prescription drug, and who possesses a pedigree for the prescription drug shall verify that each transaction recorded on the pedigree has occurred before the person may distribute the prescription drug.

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SECTION 18. 450.074 of the statutes is created to read:

450.074 Wholesale distributors; penalties. (1) A ~~person who violates a provision of ss. 450.071 to 450.073 is~~ guilty of a Class E felony.

(2) ~~Any person who engages in misrepresentation or fraud in order to distribute a prescription drug under ss. 450.071 to 450.073 is guilty of a Class E felony.~~

(3) ~~Any person who adulterates, misbrands, or counterfeits a prescription drug in order to distribute the adulterated, misbranded, or counterfeit prescription drug under ss. 450.071 to 450.073 is guilty of a Class E felony.~~ (Insert D)

(END)

2. can only require to be licensed by board of home state. The exemption stuff ???

A. Every wholesale distributor who engages in the wholesale distribution of prescription drugs must be licensed by the State licensing authority in the State in which it resides, and every non-resident wholesale distributor must be licensed in a State if it ships prescription drugs into that State, in accordance with this Act before engaging in wholesale distributions of wholesale prescription drugs. The State licensing authority shall exempt manufacturers from any licensing and other requirements of this section, to the extent not required by Federal law or regulation, unless particular requirements are deemed necessary and appropriate following rulemaking.

B. Bond Requirement - The State licensing authority shall require every wholesale distributor applying for a license to submit a bond of at least $100,000, or other equivalent means of security acceptable to the State, such as an irrevocable letter of credit or a deposit in a trust account or financial institution, payable to a fund established by the State pursuant to paragraph (g). The purpose of the bond is to secure payment of any fines or penalties imposed by the State and any fees and costs incurred by the State regarding that license, which are authorized under State law and which the licensee fails to pay 30 days after the fines, penalties, or costs become final. The State may make a claim against such bond or security until 1 year after the licensee's license ceases to be valid. The bond shall cover all facilities operated by the applicant in the state. (g)The State licensing authority shall establish a fund, separate from its other accounts, in which to deposit the wholesale distributor bonds.

Q? Unneeded Q?

C. Prescription drugs furnished by a manufacturer or wholesale distributor shall be delivered only to the premises listed on the license; provided that the manufacturer or wholesale distributor may furnish prescription drugs to an authorized person or agent of that person at the premises of the manufacturer or wholesale distributor if:

(1) The identity and authorization of the recipient is properly established; and

(2) This method of receipt is employed only to meet the immediate needs of a particular patient of the authorized person.

D. **Penalties** (It important to distinguish between knowing and unknowing.)

class E

(a) Unknowing Violations - If a person engages in the wholesale distribution of prescription drugs in violation of this Act, the person may be imprisoned for not more than 15 years, and fined not more than $50,000, or both.

Way over 5yr fine

(b) Knowing Violations – If a person knowingly engages in wholesale distribution of prescription drugs in violation of this Act, the person shall be imprisoned for any term of years, or fined not more than $500,000, or both.

Class D

Look at the 5yr fine 25,000 or life

LRB–3021/P1
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450.01 **(13r)** "Normal distribution channel" means a chain of custody for a medication that goes from a manufacturer to a wholesale distributor to a pharmacy or a chain pharmacy warehouse to a patient.

SECTION 7. 450.01 (14m) of the statutes is created to read:

450.01 **(14m)** "Pedigree" means a document or electronic file containing information that records each distribution of a prescription drug within the distribution channel.

SECTION 8. 450.01 (21m) of the statutes is created to read:

450.01 **(21m)** "Repackage" means to repack or otherwise change the container, wrapper, or label of a prescription drug. Repackaging does not include the

administration, delivery, or distribution of a prescription drug by a pharmacist to a patient.

SECTION 9. 450.01 (23) of the statutes is created to read:

450.01 **(23)** "Wholesale distribution" does not include:

(a) Intracompany sales of prescription drugs.

(b) The administration, delivery, dispensing, sale, purchase, distribution, trade, or transfer of a prescription drug or offer to sell, purchase, distribute, trade, or transfer a prescription drug for emergency medical reasons.

(c) The distribution of prescription drug samples by a manufacturer's representative.

(d) Drug returns, when conducted by a hospital, health care facility, retail pharmacy, or charitable institution.

(e) The sale of minimal quantities of prescription drugs by retail franchises to licensed health care providers for office use.

(f) The practice of pharmacy.

(g) The sale, transfer, merger, or consolidation of all or part of the business of a pharmacy or pharmacies from or with another pharmacy or pharmacies, whether accomplished as a purchase and sale of stock or business assets.

SECTION 10. 450.01 (24) of the statutes is created to read:

450.01 **(24)** "Wholesale distributor" means a person engaged in the wholesale distribution of prescription drugs, including but not limited to repackagers, own–label distributors, private label distributors, jobbers, brokers, warehouses, including manufacturers' and distributors' warehouses, and drug wholesalers or distributors, independent wholesale drug traders, and retail pharmacies or chain pharmacy warehouses that conduct wholesale distribution.

SECTION 11. 450.07 (title) of the statutes is amended to read:

450.07 (title) **Manufacturers ~~and distributors~~; licensure.**

SECTION 12. 450.07 (2) of the statutes is repealed.

SECTION 13. 450.07 (3) of the statutes is repealed.

SECTION 14. 450.07 (4) (b) (intro.) of the statutes, as affected by 2005 Wisconsin Act 14, is amended to read:

450.07 **(4)** (b) (intro.) The board shall adopt rules prescribing minimum standards for manufacturing ~~and distributing~~ drugs. Rules adopted under this paragraph may not impose requirements regarding the storage of a controlled substance in a safe, a steel cabinet, a vault, or any other secure storage compartment, area, room, or building unless one of the following applies:

SECTION 15. 450.071 of the statutes is created to read:

450.071 Wholesale distributors; licensure. (1) No person may engage in the wholesale distribution of a prescription drug in this state without obtaining a license, for each facility it operates, from the board.

(2) An applicant shall submit a form provided by the board showing all of the following and swear or affirm the truthfulness of each item in the application:

(a) The name, business address, and telephone number of the applicant.

(b) All trade or business names used by the applicant.

(c) Names, addresses, and telephone numbers of contact persons for all facilities used by the applicant for the storage, handling, and distribution of prescription drugs.

(d) The type of ownership or operation for the applicant's business.

(e) If the applicant's wholesale distribution business is a partnership, the name, address, title, and telephone number of each partner, and the name of the partnership.

(f) If the applicant's wholesale distribution business is a corporation, the name, address, title, and telephone number of each corporate officer and director, the name of the corporation, and the state of incorporation.

(g) If the applicant's wholesale distribution business is a sole proprietorship, the name of the sole proprietor and the name of the business entity.

(h) A list of all licenses and permits issued to the applicant by any other state that authorizes the applicant to purchase or possess prescription drugs.

(i) The name, address, and telephone number of a designated representative.

(j) For the person listed in par. (i), a personal information statement that contains all of the following:

1. The person's date and place of birth.

2. The person's places of residence for the past 7 years.

3. The person's occupations, positions of employment, and offices held during the past 7 years.

4. The name and addresses for each business, corporation, or other entity listed in subd. 3.

5. A statement regarding whether the person has been, during the past 7 years, the subject of any proceeding for the revocation of any license or been prosecuted for any criminal offense, and the disposition of the proceeding or prosecution.

6. A statement regarding whether the person has been, during the past 7 years, enjoined, either temporarily or permanently, from possessing, controlling, or

distributing any prescription drug, and a description of the circumstances surrounding the injunction.

7. A description of any involvement by the person with any business, including investments, other than the ownership of stock in a publicly traded company or mutual fund, during the past 7 years, that manufactured, administered, prescribed, distributed, or stored pharmaceutical products or drugs, and a list of any lawsuits in which such a business was named as a party.

8. A photograph of the person taken within the previous 30 days.

(3) Upon receipt of the application and information required in sub. (2), the board shall conduct a physical inspection of the facility from which the applicant intends to engage in the wholesale distribution of prescription drugs.

(4) The board shall grant a license to the applicant to engage in the wholesale distribution of prescription drugs if the inspection conducted pursuant to sub. (3) satisfies requirements adopted by the board for wholesale distribution facilities and if the designated representative listed by applicant:

(a) Is at least 21 years old.

(b) Has been employed full time for at least 3 years in a pharmacy or with a wholesale prescription drug distributor in a capacity related to the administration, dispensing, and distribution of, and record keeping related to, prescription drugs.

(c) Has received a score of 75 percent or more on an examination designed and administered by the board that tests the applicant's knowledge of state and federal laws regarding the wholesale distribution of prescription drugs.

(d) Is employed by the applicant full time in a managerial level position.

(e) Is physically present at the wholesale prescription drug distributor's facility during regular business hours and is involved in and aware of the daily operation of

the wholesale prescription drug distributor. This paragraph does not preclude the designated representative from taking authorized sick leave and vacation time or from being absent from the facility for other authorized business or personal purposes.

(f) Is a designated representative for only one applicant at any given time.

(g) Has not been convicted of violating any federal, state, or local law relating to wholesale or retail prescription drug distribution or distribution of a controlled substance.

(h) Has not been convicted of a felony.

(i) Submits to the department 2 fingerprint cards, each bearing a complete set of the applicant's fingerprints. The department of justice may provide for the submission of the fingerprint cards to the federal bureau of investigation for the purposes of verifying the identification of the applicant and obtaining the applicant's criminal arrest and conviction record.

(5) The board may set, by rule, continuing education requirements for designated representatives under this section.

(6) The board may determine, by rule, requirements for surety bonding or other liability coverage that each wholesale distributor licensed under this section shall carry in order to be licensed. ↑ Insert B

SECTION 16. 450.072 of the statutes is created to read:

450.072 Wholesale distributors; restrictions on transactions. **(1)** A wholesale distributor shall receive prescription drug returns or exchanges from a pharmacy or chain pharmacy warehouse pursuant to the terms and conditions of the agreement between the wholesale distributor and the pharmacy or chain pharmacy warehouse. Returns or exchanges made under this section shall not be subject to the

requirements of s. 450.073, but no wholesale distributor shall permit the entry of adulterated or counterfeit product during a return or exchange of product.

(2) (a) A manufacturer or wholesale distributor may distribute a prescription drug only to a person who is licensed or authorized by the state to receive a prescription drug. The manufacturer or wholesale distributor has an affirmative duty to verify the person's license or state authorization before it distributes a prescription drug to the person.

(b) A manufacturer or wholesale distributor may distribute a prescription drug only to the premises listed on the person's license or authorization unless all of the following are true:

1. The manufacturer or wholesale distributor distributes the prescription drugs to an authorized agent of the person at the premises of the manufacturer or wholesale distributor.

2. The manufacturer or wholesale distributor documents the authorized agent's name and address.

3. This method of distribution is necessary to promote or protect the health or safety of the authorized agent's patient.

(c) A manufacturer or wholesale distributor may distribute a prescription drug to a hospital pharmacy receiving area if a licensed pharmacist or another authorized recipient signs, at the time of the distribution, a receipt that shows the type and quantity of prescription drugs distributed.

(d) No manufacturer or wholesale distributor may accept payment for, or allow the use of, a person's credit to establish an account for the purchase of a prescription drug from any person other than the owner of record, the chief executive officer, or the chief financial officer listed on the license or authorization of a person who may

receive prescription drugs. Any account established for the purchase of prescription drugs shall bear the name of the licensed or authorized person.

SECTION 17. 450.073 of the statutes is created to read:

450.073 Wholesale distributors; pedigree. (1) Each wholesale distributor shall establish and maintain an inventory and record of all transactions regarding the receipt and distribution or other disposition of a prescription drug. The records shall include a pedigree for each prescription drug that leaves the normal distribution channel. This section does not apply to a retail pharmacy or a chain pharmacy warehouse unless the pharmacy or chain pharmacy warehouse engages in the wholesale distribution of prescription drugs.

(2) A pedigree shall contain all necessary identifying information concerning each sale or point of distribution in the chain of the distribution of the prescription drug from the manufacturer until final sale or distribution to a pharmacy or a person dispensing or distributing the prescription drug. At a minimum, the pedigree shall include:

(a) The name, address, telephone number, and, if available, electronic mail address of each recipient or distributor of the prescription drug in the chain of distribution, until the final sale or distribution that is described in sub. (2) (intro.).

(b) The address of each location from which the prescription drug was distributed, if different from the address provided in par. (a).

(c) The date of each distribution.

(d) Certification that each recipient authenticated the pedigree before distribution of the prescription drug to the next point in the chain of distribution.

(e) The name, dosage strength, size and number of containers, lot number, and name of the manufacturer for each prescription drug.

(3) The board may require, after December 31, 2007, wholesale distributors to maintain an electronic pedigree. The board may determine, after consultation with prescription drugs manufacturers, wholesale distributors, and pharmacies, when to require all wholesale distributors to maintain an electronic pedigree.

(4) Each person who is engaged in the wholesale distribution of a prescription drug, including a repackager but not including the original manufacturer of the prescription drug, and who possesses a pedigree for the prescription drug shall verify that each transaction recorded on the pedigree has occurred before the person may distribute the prescription drug.

(5) Each pedigree shall be maintained by the final recipient in the chain of distribution and by the wholesale distributor for 3 years from the date of sale or distribution.

SECTION 18. 450.074 of the statutes is created to read:

450.074 Wholesale distributors; penalties. **(1)** A person who violates any provision of ss. 450.071 to 450.073 is guilty of a Class E felony.

(2) Any person who engages in misrepresentation or fraud in order to distribute a prescription drug under ss. 450.071 to 450.073 is guilty of a Class E felony.

(3) Any person who adulterates, misbrands, or counterfeits a prescription drug in order to distribute the adulterated, misbranded, or counterfeit prescription drug under ss. 450.071 to 450.073 is guilty of a Class E felony.

(END)

negligently

any

X (2) A person who intentionally violates any provision of ss. 450.071 to 450.073 is guilty of a Class D felony.

2005–2006 DRAFTING INSERT
FROM THE
LEGISLATIVE REFERENCE BUREAU

LRB–3021/P2ins
PJH:kjf:rs

INSERT A:

INSERT B:

The board shall require every wholesale distributor to submit a surety bond acceptable to the board of at least $100,000, or other equivalent means of security acceptable to the board.

3021

Hurley, Peggy

From: Raschka, Adam
Sent: Friday, January 13, 2006 1:53 PM
To: Hurley, Peggy
Subject: RE: Hopefully the last changes to lrb 3021/2

That will work just fine. Thanks Peggy. I assume this wouldn't take very long to get drafted?

From: Hurley, Peggy
Sent: Friday, January 13, 2006 11:57 AM
To: Raschka, Adam
Subject: RE: Hopefully the last changes to lrb 3021/2

Hi Adam,

I talked this over with Mike Dsida, who drafts in criminal areas, and he suggested just saying "anyone who violates . . . " and "anyone who intentionally violates . . . ".

From: Raschka, Adam
Sent: Friday, January 13, 2006 11:07 AM
To: Hurley, Peggy
Subject: RE: Hopefully the last changes to lrb 3021/2

We're concerned that negligently is too high of a standard. Is there a different term we can use?

From: Hurley, Peggy
Sent: Friday, January 13, 2006 11:01 AM
To: Raschka, Adam
Subject: RE: Hopefully the last changes to lrb 3021/2

Hi Adam,

I can make the first two changes, but "unknowingly" is not used in the statutes. The correct term is negligently (as opposed to knowingly).

Peggy

From: Raschka, Adam
Sent: Friday, January 13, 2006 10:59 AM
To: Hurley, Peggy
Subject: Hopefully the last changes to lrb 3021/2

Peggy, can you please make the following changes to lrb 3021/2. Thanks for your help on this.

1. Add as the final sentence to Section 14, page 4, line 8, the following sentence.
"The board shall exempt manufacturers from any licensing and other requirements of this section, to the extent not required by Federal law or regulation, unless particular requirements are deemed necessary and appropriate following rulemaking."

2. Add as the final sentence to Section 16, page 8, line 25: "This section does not apply to a transfer from a manufacturer's warehouse to a wholesale distributor."

3. Change section 17, page 10, line 1: replace negligently to unknowingly.